11-0900-16358-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendments to Rules Governing Communicable Disease Reporting, Minnesota Rules, Chapter 4605

REPORT OF THE ADMINISTRATIVE LAW JUDGE

A hearing concerning the above rules was held by Administrative Law Judge Barbara L. Neilson at 9:00 a.m. on February 14, 2005, at the Minnesota Department of Health, 717 Delaware Street S.E., Minneapolis, Minnesota.

That hearing and this Report are part of a rulemaking process that must occur under the Minnesota Administrative Procedure Act[1] before an agency can adopt rules. The legislature has designed that process to ensure that state agencies—here, the Minnesota Department of Health—have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the Agency may have made after the proposed rules were initially published do not result in them being substantially different from what the Agency originally proposed. The rulemaking process also includes a hearing to allow the Agency and the Administrative Law Judge reviewing the proposed rules to hear public comment about them.

Patricia Segal Freeman, Policy Analyst/Rule Writer, Department of Health, Immunization, Tuberculosis and International Health Section, P.O. Box 9441, St. Paul, MN 55440-9441, appeared at the rule hearing on behalf of the Department of Health. The members of the Agency's hearing panel were Richard Danila, Epidemiologist and Manager of the Acute Disease Investigation and Control Section; Kristen Ehresmann, Manager of the Immunizations, Tuberculosis, and International Health Section; Franci Livingston, Assistant Manager of the Acute Disease Investigation and Control Section. Approximately 25 persons attended the hearing; 22 signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed amendments to these rules.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another twenty calendar days--that is, until March 7, 2005--to allow interested persons and the Department to submit written comments. Following the initial comment period, Minnesota law[2] required that the hearing record remain open for another five business days to allow interested parties and the Department to respond to any written comments. The hearing record closed for all purposes on March 14, 2005.

NOTICE

The Department must make this Report available for review by anyone who wishes to review it for at least five working days before the Department takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Department makes changes in the rules other than those recommended in this report, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department of Health must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, she will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Department, and the Department will notify those persons who requested to be informed of their filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Nature of the Proposed Rules

1. This rulemaking proceeding involves a proposal by the Minnesota Department of Health to amend and add additional language to rule provisions currently set forth in Minnesota Rules Chapter 4605. These rules relate to the reporting of communicable diseases and have not undergone major revision since 1985. Among other matters, the proposed rules seek to add thirteen additional infectious diseases to the reportable disease rule; require mandated reporters and medical laboratories to submit “clinical materials” rather than “isolates” to the Department's Public Health Laboratory; enable the Commissioner of Health to request clinical materials from animals from veterinarians and veterinary medical laboratories; allow the Commissioner to select certain diseases for sentinel surveillance under specified criteria; add cases involving “emerging drug resistance” and “unexplained critical illness in a previously healthy individual” to the current rule that requires the reporting of unusual cases; require the reporting of syndromes suspected to be of infectious origin and previously controlled or eradicated diseases under certain circumstances; require reporters to include on their disease report (to the extent known) the person’s gender, vaccination history for the disease reported, and pregnancy status and expected due date of delivery if the infection can be transmitted during pregnancy or delivery; and add HIV to the list of sexually-transmitted diseases for which health care providers must provide education on preventing transmission and having contacts tested.

2. The Department formed a Communicable Disease Rule Advisory Committee to assist in developing the proposed rules. The Advisory Committee included various parties affected by the proposed rule amendments, such as hospitals, infectious disease physicians, pediatricians, infection control practitioners, long-term care facilities, nurses, school nurses, veterinarians, medical laboratories, medical examiners, local public health agencies, the HIV/AIDS community, and the privacy community. Advisory Committee meetings were held on February 9, 2004, March 9, 2004, and May 18, 2004. The Department modified the proposed rules after each meeting in response to comments by members of the Advisory Committee. The Department also asked Advisory Committee members to distribute a draft of the proposed amendments to the members of their organizations during the Request for Comment period.[3]

Rulemaking Legal Standards

3. Under Minn. Stat. § 14.14, subd, 2, and Minn. Rule 1400.2100, one of the determinations which must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, the Agency may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or the Agency may simply rely on interpretation of a statute, or stated policy preferences.[4] The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the proposed rules. At the hearing, the Department primarily relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by the Agency Panel at the public hearing.

4. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.[5] Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.[6] A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.[7] The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[8] An agency is entitled to make choices between possible approaches as long as the choice made is rational. Generally, it is not the proper role of the Administrative Law Judge to determine which policy alternative presents the "best" approach since this would invade the policy-making discretion of the agency. The question is rather whether the choice made by the agency is one a rational person could have made.[9]

5. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the Department complied with the rule adoption procedure, whether the rule grants undue discretion, whether the Department has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the

rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.[10]

6. Because the Department suggested changes to part 4605.7500 of the proposed rules after original publication of the rule language in the State Register, it is also necessary for the Administrative Law Judge to determine if the new language is substantially different from that which was originally proposed.[11] The standards to determine if the new language is substantially different are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice," the differences "are a logical outgrowth of the contents of the . . . notice of hearing and the comments submitted in response to the notice," and the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question." In reaching a determination regarding whether modifications are substantially different, the Administrative Law Judge is to consider whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests," whether "the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing," and whether "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."[12]

Compliance with Procedural Rulemaking Requirements

7. On March 1, 2004, the Department published a Request for Comments pertaining to the proposed rules in 28 State Register 1056.[13]

8. The Department mailed the Request for Comments to all persons who had registered to be on the Department's rulemaking mailing list; posted the Request for Comments and a copy of the draft rules on the Department's communicable disease rule web site; provided a copy of the Request for Comments, a draft copy of the rules, and a web link to the proposed rules to members of the Communicable Disease Reporting Rule Advisory Committee, and asked them to forward this information to their colleagues and the organizations they represented; published a summary of the Request for Comments and notification about where additional information could be obtained in three Department newsletters; and published a summary of the Request for Comments and a web link to the proposed rules via e-mail to various individuals, groups, and organizations in Minnesota (including infectious disease physicians, medical laboratories, the Minnesota Chapter of the National Association of Pediatric Nurses and Practitioners, the Minnesota Medical Association, the Minnesota Academy of Pediatrics, the Minnesota Academy of Family Physicians, the Minnesota Nurses Association, physician assistant groups, early childhood providers, the Minnesota Council of Health Plans, Minnesota school nurses, child care health consultants and licensors, community health services administrators, public health nursing directors, the State Community Health Services Advisory Committee, the Minnesota AIDS Project,

and the Disease Prevention and Control Leadership Team) and asked them to post the information on their websites.[14]

9. On December 13, 2004, the Department requested the scheduling of a hearing regarding the proposed rules and filed the following documents with the Chief Administrative Law Judge:

a. a copy of the proposed rules certified by the Revisor of Statutes;

b.a copy of the Dual Notice of Hearing proposed to be issued; and

c.a draft of the Statement of Need and Reasonableness ("SONAR").

10. On December 14, 2004, the Department's Dual Notice of Hearing and Additional Notice Plan were approved by the Administrative Law Judge.

11. On December 23, 2004, the Department mailed a copy of the SONAR to the Legislative Reference Library as required by law.[15]

12. On December 27, 2004, the Department mailed the Dual Notice of Hearing and a summary of the proposed rules to all persons and associations on the Department's rulemaking mailing list.[16] On December 27, 2004, the Department also provided a copy of the Dual Notice of Hearing, the SONAR, a summary of the substantive rule changes, and a web link to the proposed rules to members of the Advisory Committee and asked them to forward this information to their colleagues and the organizations they represent. Between December 27, 2004, and January 3, 2005, the Department sent copies of the proposed rules, the Dual Notice of Hearing, the SONAR, and the summary of substantive rule changes through e-mail and listservs to the Immunization Action Coalition, infectious disease physicians through the North Central Chapter of the Infectious Disease Society of America, the Department's Infection Control Practitioner list, the Minnesota Academy of Family Physicians, the Minnesota Chapter of the American Academy of Pediatrics, the Minnesota Council of Health Plans, the Minnesota Hospital Association, the Minnesota Medical Association, the Minnesota Medical Group Management Association, the Minnesota Nurses Association, physician assistant groups, veterinarians and veterinary labs through the Advisory Committee member representing veterinarians, coroners and medical examiners through the Advisory Committee member representing medical examiners, local public health agencies, the Department's Minnesota Laboratory System list, the Minnesota Interlaboratory Microbiology Association, early childhood providers, childcare licensors, childcare resource and referral agencies, childcare health care consultants, and Minnesota school nurses.[17] The Department also has discussed the proposed hearing and rules at meetings held since December 30, 2004, published information on the proposed rules in a Departmental newsletter that is sent to over 900 persons, and discussed the proposed rules in weekly briefings sent to all Department staff.[18]

13. On December 27, 2004, a copy of the proposed rules and the Notice of Hearing were published at 29 State Register 746.[19] Those documents, the SONAR, and a rule summary were also posted on the Department's web site on December 27, 2004.[20] The Department also issued a press release on January 2, 2005, concerning the proposed rules.[21]

14. The Notice of Hearing and SONAR were mailed on December 29, 2004, to the chairs and ranking minority members of the Senate Health and Human Services Committee Budget Division, the Senate Health and Family Security Committee, and the House Health Policy and Finance Committee, as well as to Representative Mary Liz Holberg.[22]

15. Approximately eighty-four persons requested that a hearing be held on the proposed rules.[23]

16. On February 2, 2005, the Department mailed a Notice of Hearing to all persons who requested a hearing and who provided their mailing address, and e-mailed a Notice of Hearing to all persons who requested a hearing through e-mail but did not provide their mailing address.[24]

17. On the day of the hearing, the Department placed the following documents into the record:

a. the Request for Comments as published in the State Register (Exhibit A);

b. copies of the Notice of Hearing as mailed and published in the State Register, the proposed rules as certified by the Revisor of Statutes, and the SONAR, along with certificates of mailing to the Legislative Reference Library, members of the Legislature, those on the agency mailing list, and those on the agency's additional notice list (Exhibits C, D, E, F, G, H, and K);

c. copies of the written comments on the proposed rules received by the agency during the comment period (Exhibit I);

d. letters of support received from the Minnesota Medical Association, the School Nurse Organization of Minnesota, Beth Baker, M.D., M.P.H. (Program Director of the Occupational and Environmental Medicine Residency Program of Regions Hospital/Health Partners), and Edward N. Janoff, M.D., President of the North Central Infectious Disease Society of American and Professor of Medicine at the University of Minnesota School of Medicine) (Exhibits L and N); and

e.copies of the Department's powerpoint presentation and statement by Dr. Danila at the February 14, 2005, hearing (Exhibit M).

18. Twila Brase, R.N. P.H.N., President of the Citizens' Council on Health Care (CCHC), asserted that the Department "depends on groups like CCHC to do their public notification" and questioned whether the Department had done all they could do to make the proposed rules known to the media and apprise the public of the impact of the proposed rules. Paul Bearmon, M.D., also raised concerns about the process leading to the hearing and questioned whether the Department adequately disseminated notice regarding the hearing. He asserted that the Department had merely notified a small number of interested groups of its intention to change the rules and relied upon those groups to force an open discussion. Dr. Bearmon indicated that issues involving medical care and patient privacy should be left for the Legislature. During the hearing, Dr. Danila stated a belief that the Department had issued a press release regarding the fact that a hearing was going to be held. In a post-hearing e-mail exchange with CCHC, the Department clarified that it had issued a press release in January of 2005 announcing the comment period on the rules and including specific information on the hearing, but did not, in fact, issue a later news release about the February 14, 2005, hearing.

19. The Administrative Procedure Act requires that proposed rules be published in the State Register, persons on the agency rulemaking mailing list be notified of proposed rules, along with the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules, and that the agency make "reasonable efforts to notify persons or classes of persons who may be significantly affected by the rule being proposed by giving notice of its intention in newsletters, newspapers, or other publications, or through other means of communication."[25] By publishing the proposed rules in the State Register in December 2004, issuing the January 2005 press release, asking its Advisory Committee members to further distribute information to their organizations, disseminating information in Departmental newsletters, posting information on the Department website, providing required notice to certain members of the Legislature, notifying all the individuals and organizations who had asked the Department to notify them of rulemaking, providing additional notice to a broad variety of other persons and organizations as detailed above, sending information about the hearing to all persons who requested that a hearing be held or otherwise sent in a comment during the comment period, the Administrative Law Judge finds that the Department satisfied the notice requirements set forth in the Minnesota Administrative Procedure Act.[26]

20. The Administrative Law Judge concludes that the Department met all of the procedural requirements established by statute and rule.

Statutory Authority

21. As statutory authority for the proposed rules, the Department cites Minn. Stat. §§ 144.12, subd. 1, and 144.05, subd. 1. Minn. Stat. § 144.12, subd. 1, states that

the Commissioner of Health "may adopt reasonable rules pursuant to chapter 14 [the Minnesota Administrative Procedure Act] for the preservation of the public health." This statute goes on to state that the Commissioner "may control, by rule, . . . [t]he treatment . . . of persons suffering from communicable diseases, including all manner of venereal disease and infection, . . . and the reporting of sicknesses and deaths from them." The list of duties set forth in Minn. Stat. § 144.05, subd. 1, includes authorization for the Commissioner of Health to "conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems," and "establish and enforce health standards for the protection and the promotion of the public's health such as . . . reporting of disease . . . ."

22. During the hearing and in post-hearing comments, CCHC questioned whether the Department has proper statutory authority to modify the rules as proposed, based upon an assertion that the statutes cited by the Department merely provide a general description of the Commissioner's duties and not an explicit statutory authorization. CCHC, Dr. Bearmon, Barbara Creswell, and others also expressed concern that the Department was thwarting the legislative process in proposing the rules and indicated that the modifications should be submitted to the Legislature. CCHC noted that the Department has gone to the Legislature in the past to seek rulemaking authority and contended that the Department's interpretation of Minn. Stat. § 144.05 and 144.12 is unconstitutionally broad.

23. In its post-hearing response, the Department disagreed with this characterization of the statutes upon which it relies. The Department emphasized that the statutes upon which it relies clearly convey rulemaking authority for the reporting of communicable disease and the preservation of public health. The Department pointed out that it has had statutory authority to require the reporting of sicknesses and disease from communicable diseases since at least 1905 and the Minnesota courts have long recognized that the preservation of public health is an inherent sovereign duty that finds ample support in the police power.[27] Moreover, the Department noted that it had notified the required members of the Legislature of the proposed rules and the Legislature could, if it wished, overrule the proposed rules or limit the Department's authority.

24. The Administrative Law Judge finds that the Department has the statutory authority to adopt the proposed rules. The Department has appropriately made members of the Legislature aware of the proposed rule and is permitted to proceed with rulemaking rather than seeking the passage of legislation.

Impact on Farming Operations

25. Minn. Stat. § 14.111 imposes an additional notice requirement when rules are proposed that affect farming operations. In essence, the statute requires that an agency must provide a copy of any such proposed rule change to the Commissioner of Agriculture at least thirty days prior to publishing the proposed rule in the State Register.

26. The proposed rules do not impose restrictions or have a direct impact on fundamental aspects of farming operations. The Administrative Law Judge finds that the proposed rule change will not affect farming operations in Minnesota, and thus finds that no additional notice is required.

Cost and Alternative Assessments in the SONAR

27. Minn. Stat. § 14.131 requires an agency adopting rules to include in its SONAR:

> a.a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;
>
> b.the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;
>
> c.a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
>
> d.a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;
>
> e.the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;
>
> f.the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals; and
>
> g.an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

28. The statute also requires that the SONAR must also "describe how the agency, in developing the rules, considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002."

29. The SONAR includes a discussion of the analysis that was performed by the Department to meet the requirements of this statute.[28]

30. With respect to the first requirement, the Department indicated that the proposed rules do not change who is required to report, but rather what must be reported. It stated that the classes of persons who will be affected by the proposed changes are health care providers responsible for reporting (i.e., physicians, infection control practitioners or other persons designated by a health care facility to report, and all other licensed health care providers who provide care to a patient who has or is suspected to have a reportable disease or condition); hospitals, nursing homes, medical clinics and other health care facilities whose personnel must report communicable diseases and conditions; medical laboratories required to report test results and submit clinical materials on reportable diseases and conditions; veterinarians and veterinary laboratories required to report disease and submit clinical materials; school nurses; coroners and medical examiners; persons in charge of institutions, schools, child care facilities, or camps; the general public and all visitors to the state who acquire a reportable disease or condition, or who come in contact with a person who has a reportable disease or condition; the Minnesota Department of Health; and local public health agencies. The Department indicated that mandated reporters and the Department of Health are the classes of persons who will bear the costs of the proposed rule, and stated that Minnesota residents and visitors and mandated reporters will benefit from the proposed rules. The Department indicated that Minnesota residents and visitors will benefit because the proposed rules will ensure that Minnesota's communicable disease reporting system will be revised to reflect new diseases and laboratory methods, and thereby maintain the Department's ability to properly investigate and control communicable disease in the state, implement control measures, and ensure that people exposed to communicable diseases receive preventive drug therapy when appropriate. The Department believes that mandated reporters also will benefit from updated rules because the Department will quickly alert health care providers about communicable diseases of concern and disseminate guidelines on infection control precautions, diagnosis and treatment. In addition, the Department provides assistance with communicable disease expertise through a staff of clinicians and epidemiologists, facilities assistance from the federal Centers for Disease Prevention and Control ("CDC") and has the ability to perform laboratory tests that may not otherwise be available to a health care provider, such as testing for legionellosis (the bacteria that can result in Legionnaires' disease). Finally, the Department disseminates aggregate information obtained under the rules in a manner that can assist clinicians in their practice and guide them in prescribing effective treatment.

31. With respect to the second requirement, the Department estimated that the probable costs to the Department for implementing the proposed rule amendments would be minimal. It is expected that existing agency staff would be able to handle reports on the new diseases encompassed in the proposed rule, since most of the new diseases are expected to occur relatively infrequently and, if they did occur on a wide scale, Department staff would be shifted from daily activities to address the outbreak. The Department noted that there would be initial costs associated with developing and

distributing educational materials on the new rules to mandated reporters, but it is expected that these educational materials will be incorporated into the Department's regular communications. Although the Department will receive additional clinical materials under the proposed rule, particularly with respect to the requirement that clinical materials be submitted when there is a diagnosis of HIV infection including AIDS, it is anticipated that existing staff will perform tests on these materials without needing additional state funds. Minimal costs may be associated for mailing and shipping expenses. The Department does not expect that there will be any costs to any other state agency or to local public health agencies. The role of local public health agencies in assisting the Department in disease investigation would continue under the proposed rules. There will be no effect on state revenues.

32. The third requirement imposed by Minn. Stat. § 14.131 asks the Agency to determine whether there are less costly or less intrusive methods to achieve the purposes of the proposed rules. In the SONAR, the Department stated that it has proposed the least costly and least intrusive methods necessary to achieve the purpose of the rule—the reporting of communicable diseases including submission of clinical materials and other relevant information for disease surveillance, investigation, and control. The Department indicated that all states have had some form of reporting since 1901 and stated that it is not aware of any less costly method than reporting for achieving the goals of communicable disease surveillance, timely investigation, and control. In the Department's view, it would be difficult if not impossible to find a reliable substitute for monitoring disease in real time than reporting by those who have knowledge. Although some cost is associated with increasing the number of diseases for which submission of clinical materials would be required, the Department emphasized that the submission of clinical materials will permit the Department to conduct tests critical for disease monitoring and investigation. Without these tools, there could be substantial costs, including increased illness and unnecessary death. The Department noted that it was mindful of cost in drafting the proposed amendments and decided not to require the reporting of all cases of varicella zoster disease (chickenpox) because such a requirement would be too burdensome given the frequency with which the disease still occurs. Although the proposed rules require all reporters to report specified cases of varicella zoster (e.g., cases where a patient is hospitalized in an intensive care unit), the Department expects that it will conduct sentinel surveillance for varicella zoster disease and that reporting of all cases will only be required by the Commissioner if incidence of the disease decreases to a point where the Commissioner determines that sentinel surveillance can no longer provide adequate data. The Department acknowledged in the SONAR that the least costly method would be to make no revisions to the rules, but indicated that this would not ensure that communicable diseases and conditions of public health significance are reported to the Department so it can take timely action to protect public health.

33. In further considering the third requirement imposed by Minn. Stat. § 14.131, the Department stated that the proposed rule amendments could be viewed as intrusive with respect to persons whose health information is reported because they require reporting of otherwise private health information. The Department noted that the

representatives of the Minnesota Civil Liberties Union and the Minnesota AIDS Project included on the rules advisory committee did not raise issues as to the intrusiveness of the proposed rules. The Department acknowledged that the proposed rules require the reporting of additional information, including the reporting of additional diseases, the submission of clinical materials for additional diseases, the reporting of unexplained critical illness in a previously healthy person, reporting of gender as part of a disease report, reporting of information on pregnancy status as part of a disease report if an infection can be transmitted during pregnancy or delivery, and the reporting of vaccination history as part of a disease report. The proposed rules also make it clear that evaluation of the contacts of case-patients is part of the disease investigation. The Department indicated that these changes are justified in the SONAR, and indicated that it knew of no method other than reporting for conducting public health surveillance, investigation, and control of communicable diseases. Because the Department monitors disease in order to contain the spread of disease and limit illness or death and does not simply track disease trends, it needs identifying information to conduct case interviews and determine the most likely source of infection. By interviewing case-patients, the Department is able to identify their family members and other contacts who may be at risk of disease, and then make recommendations that they seek medical attention, undergo preventive drug therapy, or take infection control precautions. It also can take other actions to prevent the spread of illness, such as advising consumers not to eat certain foods. The Department noted that the federal rules adopted under HIPAA, which sets national standards for the privacy of health information, create an exemption that permits the reporting of private health information to health departments authorized by law to receive such information for the purpose of surveillance. The Department pointed out that, under the Minnesota Government Data Practices Act, health data on individuals is characterized as private and the Department can only release such data to the subject of the data and for certain public health purposes. The Department maintains that it has an excellent record of maintaining data privacy. With respect to pregnancy status, the Department emphasized that the reporting of pregnancy status is limited to situations where a woman has a reportable disease that a newborn can acquire from the mother during pregnancy or delivery, such as HIV/AIDS and hepatitis B virus. With such information, the Department can undertake efforts to help ensure prevention of infection in newborns, including education directed to clinicians and patients and recommendation of timely drug therapy. The Department does not believe there is a substitute for collecting information on pregnancy status in such situations. The proposed rules require that "vaccination history for the disease reported" be divulged as part of a disease report in order to monitor whether the occurrence of the disease represents vaccine failure. Again, the Department does not believe that there is any less intrusive substitute for obtaining vaccination history in such situations. Accordingly, the Department concluded that no less intrusive methods are available to accomplish the goals of the rules.

34. The fourth provision of Minn. Stat. § 14.131 requires the Agency to describe any alternative methods that were considered and the reasons they were rejected. In the SONAR, the Department indicated that communicable disease reporting requirements are the standard method for performing surveillance for public

health purposes in every state in the United States. Sentinel surveillance was incorporated into the proposed rules as an alternative reporting method for appropriate diseases. As discussed further below, the Department considered but rejected suggestions that the agency use a multiple timeframe approach for reporting communicable diseases rather than the one-working-day reporting requirement. The Department also considered the suggestions of some Advisory Committee members who suggested that the Department not require mandated reporters to submit test results and clinical materials when they send clinical materials to out-of-state laboratories, but also rejected these suggestions based on its belief that the approach in the proposed rules was reasonable.

35. The fifth factor required to be considered under Minn. Stat. § 14.131 is the probable cost of complying with the proposed rules. The Department anticipates that the largest portion of additional cost will be borne by hospitals and medical laboratories, and the costs borne by the Minnesota Department of Health will be minimal. The SONAR indicates that most hospitals and some large clinics and long-term care facilities have one or more infection control practitioners ("ICPs") on staff who already report communicable diseases to the Department under the existing rule. The Department acknowledged that some of the changes in the proposed rules may increase the workload of ICPs, but the Department indicated that the increase should not be substantial for any one reporter. The proposed rules add thirteen diseases to the list of reportable diseases; however, as matter of current practice, reporters already report eleven of the new diseases. The Department estimates that the new reporting requirement for neonatal sepsis will only result in the reporting of 20-25 cases per year. The remaining new disease for which reporting would be required is varicella zoster disease. The Department indicated in its SONAR that its staff would be available upon request to assist reporters with reporting. Because sentinel surveillance will be used for only a very limited number of diseases, the Department does not expect that costs to reporters will significantly increase above current levels. In response to concerns that sentinel surveillance might be burdensome for the selected sites, the Department modified part 4605.7046 of the proposed rules to require consultation with the sites and consideration of "the overall impact of sentinel surveillance on a site" prior to selection. The Department further noted that many of the requirements in the proposed rules for submission of clinical materials apply to diseases that occur infrequently. Ten of the thirteen diseases proposed resulted in a combined total of about forty disease reports in Minnesota in 2003. The two diseases reported more frequently were cryptosporidiosis (155 reports) and HIV/AIDS (200 new reports). Most clinical materials for HIV/AIDS would be submitted by one large laboratory in Minnesota, and that laboratory has informed the Department that it is able to comply with the proposed rule. The Department estimates that the proposed requirement that the pregnancy status of a person chronically infected with hepatitis B virus, HIV/AIDS, or another reportable perinatally transmissible disease be reported will result in an additional 15-20 reports relating to HIV/AIDS and 10 reports relating to hepatitis B virus.

36. The sixth factor set forth in Minn. Stat. § 14.131 requires an assessment of the probable costs or consequences of not adopting the proposed rule. The Department indicated in the SONAR that significant potential costs would be attached to

not going forward with the proposed amendments to the rules since, if the new diseases covered in the proposed rules occurred and were not reported, unnecessary illness or death could result. The Department also stated that, without the proposed requirements for the submission of clinical materials, the Department's disease investigation activities could be impeded and the public's health endangered. For example, if there were a suspected case of inhalational anthrax, the Department would perform tests to determine if the anthrax was a subtype for which antibiotics are effective to ensure effect follow-up for exposed individuals. The Department pointed out that delays in recognizing an outbreak could also result in negative economic consequences such as those suffered in Toronto during the 2003 SARS outbreak in that city. The Department emphasized the benefits associated with the proposed rule for Minnesota residents and visitors and health care providers.

37. The seventh factor set forth in Minn. Stat. § 14.131 requires consideration of the differences between the proposed rule and existing federal regulations. The Department noted in its SONAR that there are no federal regulations regarding the reporting of communicable disease, so the proposed rules do not conflict with current federal law and regulations.

38. Minn. Stat. § 14.131 imposes an additional requirement that the Department explain how it considered and implemented performance-based standards in developing the proposed rules. The Department explained in the SONAR that it considered objections to the one-working-day reporting requirement but ultimately determined that disease reporting did not lend itself to multiple timeframes because expeditious reporting may be necessary to identify an outbreak and take appropriate precautions and multiple timeframes for each disease would unduly complicate the rule. The Department noted that it will accept reporting in any format convenient for the reporter as long as the required information is included, it will assist hospitals in completing forms upon request, and it has begun to work with ICPs and others to streamline special report forms for some diseases.

39. Minn. Stat. § 14.131 also requires that the agency consult with the Commissioner of Finance to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government. The Department noted in its SONAR that it delivered a copy of the proposed rules and the SONAR to the Executive Budget Officer for the agency on November 23, 2004. The Department further indicated that it does not anticipate costs to local agencies as a result of the proposed rules. It believes that local jurisdictions will benefit from an updated system of communicable disease surveillance, investigation, and control because their residents will be better protected with early detection of an outbreak.

40. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules.

Analysis of the Proposed Rules

41. This Report is limited to the discussion of the portions of the proposed rules that received critical comment or otherwise need to be examined. Accordingly, the Report will not discuss each comment or rule part. Several sections of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. For these reasons, it is unnecessary to engage in a detailed discussion of each part and subpart of the proposed rules in this Report. The Administrative Law Judge specifically finds that the Agency has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this Report by an affirmative presentation of facts. She also finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

General Objections to Proposed Rules

Privacy Concerns

42. The existing communicable disease reporting rules set forth in part 4605, which are not a part of this rulemaking proceeding, already require reporting of patient names and other identifying information.[29] The new patient data that would be reported under the proposed amendments are gender; vaccination history for the disease reported; and pregnancy status if the infection can be transmitted during pregnancy or delivery (see part 4605.7090, subparts D, K and L, and part 4605.7044). The proposed rules also add language on "evaluating" contacts of cases and suspected cases (see part 4605.7500) and require the reporting of thirteen additional diseases (see part 4605.7040). The reasons urged by the Department for these specific modifications, along with public comments, will be discussed in the Rule by Rule Analysis below, in conjunction with the relevant rule parts.

43. Most of the written comments requesting a hearing objected to the entire set of proposed rules on privacy grounds. Several persons commented that the reporting requirements invade the privacy expected by citizens with respect to medical information and violate doctor/patient confidentiality. Many of those filing written comments suggested that reporting be allowed to occur only if patients consent to disclosure of their personal information. Dr. Bearmon suggested that the entire proposal be redrawn with clearer guidelines to ensure the protection of patient privacy or, in the alternative, that Legislature enact a bill specifying that the state has no right to collect private medical information with the express written consent of the patient except in a very limited number of clearly defined situations. Jon Folkedahl also objected to the rules due to the lack of requirement for patient consent to attach their names and other personal identifying information to the collected information, and expressed concern that such information might be mishandled or misused and become available to others without the permission of the patient. Mike Moline raised individual and group privacy concerns regarding the proposed rules as well, particularly relating to the HIV-positive community, and questioned whether informing the Department of private medical information might do more harm than good.[30] Martin Kellogg[31] and Tyler Clements[32] also objected during the hearing to the invasion of privacy associated with the proposed

rules, and Spencer Johnson, Shirley Klenk, Elizabeth Cantrell, and Lynn Park raised privacy concerns in their requests for hearing on the proposed rules.[33]

44. In its SONAR, hearing testimony, and post-hearing responses, the Department indicated that, while it recognizes that individuals have concerns about privacy, a core function of public health is to take measures to control the spread of infectious disease. The Department contends that the backbone of this core function is the communicable disease reporting rules. Dr. Harry Hull, State Epidemiologist and Division Director of the Department's Infectious Disease Epidemiology, Prevention and Control Division, and Dr. Robert Danila, Assistant State Epidemiologist and Manager of the Department's Acute Disease Investigation and Control Section, explained during the hearing that reporting of communicable disease is central in the Department's effort to protect the health of the public. They indicated that each individual state has its own long-standing disease surveillance system and disease reporting requirements. They further stated that the reporting of infectious diseases allows the Department to identify outbreaks and health threats, monitor trends in infectious diseases, and take prompt action to protect the public such as eliminating contaminated food or making recommendations for infection control precautions. Dr. Hull stated that establishment of a list of reportable diseases is a vital and necessary tool for the control of infectious diseases in Minnesota, and emphasized that a new, updated list of reportable diseases is necessary to allow the Department to fulfill its responsibility to protect Minnesota citizens from death and disability due to infectious diseases. This is particularly the case in light of new and emerging diseases and the possibility of the intentional spread of infectious agents through terrorism. The reporting rules ensure that health professionals know what should be reported, in what fashion, and how quickly, and also make it clear what does not need to be reported. By monitoring the occurrence of infectious disease, the Department is able to ascertain when something unusual is happening and evaluate the effectiveness of its programs.

45. The Department points out that, once health data is in the hands of a government agency, it is classified as "private" under the Minnesota Government Data Practices Act and may only be released to the subject of the data or used for certain public health purposes.[34] The Department asserts that reporting of identifiable health information is the standard and accepted method of disease surveillance, as reflected in the HIPAA rules. Under those rules, "covered entities" may disclose protected health information to health departments authorized by law to receive such information for the purpose of disease reporting and surveillance, without the written authorization of the individual. The Department argues that the reporting of health data under the rules is both necessary and reasonable.

46. Beth Baker, M.D., M.P.H., Program Director of the Occupational & Environmental Medicine Residency Program of Regions Hospital/HealthPartners, and Past Chair of the Public Health Committee of the Minnesota Medical Association, also supported the proposed amendments to the communicable disease rules. Dr. Baker noted that it is important for the Department to track infectious and communicable diseases for public health purposes and to monitor whether there is a developing epidemic of a particular infectious disease, and indicated that the proposed

amendments would help better define and clarify data that needs to be collected. She noted that similar data has been collected by the Department for years and is also collected by health departments in other states.[35]

47. Edward N. Janoff, M.D., President of the North Central Infectious Disease Society of America and Professor of Medicine at the University of Minnesota School of Medicine, indicated that "[c]ollecting relevant information from individual patients is essential to control and prevent disease, as is maintaining the integrity and privacy of that information." He further noted that the Department needed the appropriate tools to serve the public effectively.[36] In his testimony at the rule hearing, Dr. Janoff stated that the control of disease depends upon direct contact with the public and with the individual patients affected by the disease. [37]

48. The Minnesota Medical Association expressed support for the proposed amendments, noting that "[o]ne of the most basic and essential components of a strong public health system is disease surveillance, investigation, and containment." The MMA indicated that the "rapid changes that occur in medical technology and disease treatment, as well as the appearance of new disease threats (e.g., SARS and bio-terrorism agents), require a regulatory structure that is both responsive to and flexible in addressing what are very real threats to an individual's and the public's health." Although the MMA acknowledged that "[p]atient privacy and confidentiality is sacred to physicians," it stated that "physicians also recognize that there may be occasions in which release of private health information is critical to protecting the health of the population. While it can be a significant challenge to find the right balance, the MMA recognizes that current state and federal law has established those boundaries." The MMA also noted the Department's "excellent history in maintaining privacy" and its belief that "the proposed rules reasonably require the reporting of information in the interest of protecting the health and safety of the population."[38]

49. The School Nurse Organization of Minnesota also endorsed the proposed amendments and recognized that "these revisions are critical to respond to new and emerging diseases, to stop the spread of disease and to keep our citizens healthy" and were in compliance with HIPAA.[39]

50. The Minnesota AIDS Project (MAP) also supported many of the proposed revisions to the rules. In its letter of support, MAP noted that Minnesota was the first state to enact names-based reporting procedures for HIV surveillance and indicated that the Department had carefully managed this data so as to prevent unintended or unwarranted disclosure. MAP thus has confidence that the Department will handle such information confidentially and will use it only for the intended purposes. In its letter of support, MAP commended the Department "for its history of responsibly managing information collected for public health surveillance." While MAP noted that medical data privacy continues to be a concern for the HIV community, it is a concern that "we have had to balance with the equally compelling need for aggregated data to help us design effective interventions and target our efforts. Based on our experience, we believe this delicate balance has been well managed and trust this will be so in the future as long as our department of health adheres to the professional standards of public health."

51. The Minnesota Council of Health Plans (MCHP), whose members include Blue Cross Blue Shield of Minnesota, First Plan of Minnesota, Health Partners, Medica, Metropolitan Health Plan, Preferred One, Sioux Valley Health Plan of Minnesota, and UCare of Minnesota, supported the proposed amendments. The MCHP characterized the reporting of communicable disease as a key component of the Department's ability to assess the health status of its population and stated that it did not believe the proposed rules violated privacy or HIPAA rules. MCHP pointed out that Minnesota law classifies health data as private and noted that the Department applies appropriate safeguards to guarantee safety.

52. Barbara Bor, R.N., Infection Control Practitioner at Fairview Northland Regional Medical Center,commented that, based upon her frequent interactions with the Department, she believes that the Department is "an outstanding State agency" that respects information she shares with them and "always honor[s] the rights and privacy of the individual." She further noted that the Department has provided data assessments and epidemiology summaries of illnesses and effective treatment and prevention measures that ultimately improve patient outcomes and reduce the consequences of infectious diseases. She further testified at the hearing that, during her dealings with the Department over a 12-year period of time, she has observed "an utmost respect of patient confidentiality."[40]

53. Neal Holton, M.D., M.P.H., Medical Director of the St. Paul – Ramsey County Department of Health and former Chair and current member of the Public Health Committee of the Minnesota Medical Association, provided further support for the need for disease surveillance and the investigation of disease outbreaks based upon that surveillance to ensure that public health is protected. Although he acknowledged that individual privacy may be invaded to some extent, he indicated that the MMA believed that the rule changes are consistent with the best interests of patients. Dr. Holton also noted that the Department has a long history of protecting the privacy of data it receives and there has not been any instance of that privacy being breached in any way.[41]

54. It is obviously important to protect to the greatest extent possible the privacy interests of individuals that stem from the doctor-patient relationship. However, the reporting of infectious diseases to the Department to ensure protection of public health and quick response to threats to public health is also very important and has a long history in Minnesota. Minnesota statutes recognize the role of the Department in conducting studies and investigations, collecting and analyzing health and vital data, identifying and describing health problems, facilitating services for the prevention and control of illness and disease, and establishing and enforcing health standards for the protection and promotion of the public's health such as the reporting of disease. The Department's existing rules, which were found years ago to be needed, reasonable, and in accordance with state law, already require physicians, health care facilities, medical laboratories, veterinarians, and veterinary medical laboratories to report infectious diseases along with patient names and other identifying information to the Commissioner. The Government Data Practices Act makes it clear that health data are classified as private data on individuals which may not be disclosed except to the individual or as otherwise provided under the Act. However, the Commissioner of

Health is expressly permitted by the Government Data Practices Act to "disclose health data to the data subject's physician as necessary to locate or identify a case, carrier, or suspect case, to establish a diagnosis, to provide treatment, to identify persons at risk of illness, or to conduct an epidemiologic investigation."[42] Moreover, there is no evidence that Department staff members have inappropriately used or revealed health data on individuals; to the contrary, several individuals and organizations commended the manner in which the Department protected the confidentiality of such information. The Administrative Law Judge concludes that the Department has shown that the reporting of communicable disease information as a general matter is consistent with existing Minnesota law and rules, is necessary and reasonable to ensure adequate surveillance of infectious disease and adequate protection of public health, and does not represent an unwarranted invasion of privacy.

Medical Research Concerns

55. CCHC also objected to the proposed rules based upon a belief that the Department is attempting to further a research agency without adhering to typical regulatory requirements for medical research. The Department responded that it is not attempting to conduct research by virtue of the proposed rules, but rather is attempting to protect residents of Minnesota from unnecessary sickness and death due to infectious disease. The Department indicated that it goes through an Institutional Review Board process required by federal regulations when it conducts research, requiring demonstration that all requirements for the protection of human subjects are met.[43] The Department further noted that, under guidelines issued by the U.S. Centers for Disease Control and Prevention, the "major difference between research and non-research lies in the primary intent of the activity."[44] The guidelines go on to say that the primary intent of research is to "generate or contribute to generalizable knowledge" whereas the primary intent of non-research in public health is to "prevent or control disease or injury and improve health . . . ."

56. Here, it is evident that the Department's primary intention in proposing the rules is to benefit Minnesotans and visitors by controlling health problems in the population from which the information is gathered. This does not amount to the undertaking of research but simply reflects the Department's efforts to engage in monitoring of certain communicable diseases for the purpose of prevention and control.

.**Cost and Burdensomeness Concerns**

57. Martin Kellogg, Tyler Clements, and CCHC contended that the proposed rules are administratively burdensome, costly, and could affect patient care. CCHC expressed concern that the reporting requirements will unduly burden practitioners in the course of carrying out their responsibilities to ill patients. In particular, CCHC felt that the Department's paperwork requirements and timelines for reporting fail to take into consideration the realities of patient care, staffing issues, and time constraints.

58. Barbara Bor commented that the proposed rules will not add additional financial burdens. She pointed out that Infection Control Practitioners and nurses

conduct surveillance on a continuous basis in all health care settings in Minnesota to protect patients, health care workers, visitors, and others in the health care environment. She indicated that Infection Control Practitioners strive to carry out their duties in a timely, efficient, and cost-effective manner and that the mandatory reporting of communicable diseases assists them in achieving these goals. She urged the sharing of infectious disease information across all settings in the continuum of care in order to ensure the health of people in Minnesota. She also asserted that the reporting surveillance process has disrupted the transmission of disease, resulting in decreased health care costs.

59. In its post-hearing submissions, the Department pointed out that the members of the Advisory Committee did not feel that the proposed rules were overly burdensome or costly, and emphasized that several individuals and organizations who are affected by the proposed rules submitted letters in support of the proposed rules. For example, the Minnesota Medical Association expressed support for the proposed amendments even though it acknowledged that physicians faced reporting burdens and asked that the Department monitor the potential expanded burden imposed by virtue of the addition of the thirteen diseases and the reporting of supplemental information such as vaccination history.[45] Dr. Janoff, President of the North Central Infectious Disease Society of America, stated his impression that "the new reporting rules do not extend the amount or depth of information compared to that which was sought previously."[46] The Department further pointed out that the prompt action that will be taken by the Department under the proposed rules to ensure effective follow-up after exposure will prevent or minimize costs that would otherwise be inherent in the diseases and infections that will now be reported. In addition, as noted above, the proposed rules received support from the School Nurse Organization of Minnesota, the Minnesota AIDS Project, the Minnesota Council of Health Plans, the St. Paul-Ramsey County Department of Health, and various infection control practitioners.

60. Based upon the analysis of costs and burdens associated with the proposed rules reflected in the comments of organizations representing mandated reporters and others affected by the proposed rules, the SONAR, and the Department's post-hearing submissions, and the discussion of the public health benefits associated with the proposed rules, it does not appear that costs or burdens associated with the proposed rules render them unnecessary, unreasonable, or otherwise defective.

Concerns about Past and Future Rules

61. Several persons expressed opposition to a Departmental rule initiative that was overruled by action of the State Legislature in the past and others raised concerns about the likely scope of future rules the Department may propose. This rulemaking proceeding only addresses the set of proposed rules published by the Department in December of 2004 relating to amendments to the communicable disease reporting rules. While comments concerning other past and future rules may have been of interest to the Departmental panel and helpful in considering future directions to be taken, they are not relevant to an evaluation of the need for and reasonableness of the current proposed rules.

Part 4605.7040 – Disease and Reports; Clinical Materials Submissions

62. The proposed rules require that "clinical materials" be submitted for certain diseases listed in the existing and proposed rules. The proposed rules define "clinical materials" in part 4605.7000, subp. 3, to mean "a clinical isolate containing the infectious agent for which submission of material is required" or "if an isolate is not available, material containing the infectious agent for which submission of material is required, in the following order of preference: (a) a patient specimen; (2) nucleic acid; or (3) other laboratory material." This modification was proposed because laboratory practices have evolved since the existing rules were put in place. Because new rapid diagnostic tests are being used by laboratories across the state that do not involve isolation of a viable "isolate," the requirement in the existing rule that "isolates" of disease agents be submitted to the Department is no longer feasible. No one objected during the rulemaking proceeding to the submission of clinical materials for the specified diseases or to the definition of the term. The Department has shown that the proposed rule is reasonable and necessary in light of current laboratory testing practices.

63. In the proposed rules, the Department seeks to add thirteen diseases to the list of currently reportable diseases. These diseases are Arboviral Disease, Coccidioidomycosis, Transmissible Spongiform Encephalopathy (TSE), Orthopox virus, Severe Acute Respiratory Syndrome (SARS), Smallpox, Cyclosporiasis, Enterobacter sakazakii, Kingella, Neonatal Sepsis, Staphylococcus aureus, Varicella Zoster Disease, and Vibrio. The proposed rules require certain diseases set forth in the existing rules and proposed rules to be immediately reported by telephone to the Commissioner, while other diseases are required to be reported within one working day.

64. During the hearing, Martin Kellogg raised concerns about government bureaucracy. Mr. Kellogg objected to the long list of diseases to be reported and objected to the fact that the rules continue to require reporting of diseases that occur relatively rarely. The Department responded that this is because, when such diseases do occur, they pose a public health concern. For example, the presence of tetanus shows that an individual did not receive a tetanus vaccine booster and would prompt the Department to take steps to remind Minnesotans about the importance of booster shots. The Department is proposing to add smallpox back to the list of reportable diseases because of the threat of its possible use as a bioterrorism agent. Moreover, the proposed rules did make four diseases (chancroid, mumps, pertussis, and syphilis) reportable within one working day instead of immediately.

65. Mr. Kellogg and Tyler Clements commented at the hearing that the inclusion of a disease as a reportable disease under the rule is not necessary to bring the disease under control. As an example, they cited the fact that SARS was addressed internationally and in Minnesota despite the fact that it was not on the reportable disease list. In its post-hearing submission, the Department responded that it proceeded under part 4605.7080 of the rules to request reporting of SARS as a "newly recognized" disease and asked Minnesota hospitals to voluntarily report all suspected SARS cases. Several hospitals indicated that they would be reluctant to report unless it was mandated. It took one to two weeks for the Commissioner to conduct negotiations,

do legal research, and issue a directive to report SARS. It was fortunate that no confirmed cases of SARS occurred during this time. The Department has shown that the inclusion of a disease on the list of diseases to be reported will ensure that the delays inherent in the part 4605.7080 process are avoided and proper surveillance of the incidence of that disease occurs.

66. The SONAR and the Department's post-hearing submissions provide an ample basis for finding that the inclusion of the thirteen additional diseases is needed and reasonable to ensure monitoring of infectious disease and protection of public health, and that there are legitimate public health reasons for continuing to require reporting of the diseases encompassed in the current rules. The Department's failure to delete diseases mentioned in the current rule from the reporting requirement does not render the proposed rules defective.

Part 4605.7046 – Sentinel Surveillance

67. Sentinel surveillance is defined in the proposed rules to mean "monitoring a disease or syndrome through reporting of cases, suspected cases, and carriers and submission of clinical materials by selected sites . . . ."[47] The Department conducts sentinel surveillance in order to get a representation of disease activity in the state. In its SONAR and during the hearing, the Department explained that this portion of the proposed rules is based on the assumption that, for some communicable diseases, public health purposes can be achieved by receiving reports from selected sites rather than by having all health care providers or facilities submit reports, thereby reducing the volume of reporting for the state as a whole. Under the proposed rules, the Commissioner may select an infectious disease or syndrome for sentinel surveillance if the Commissioner determines that "sentinel surveillance will provide adequate data for epidemiological purposes and the surveillance is necessary for: A. characterization of the pathogen; B. monitoring vaccine effectiveness; or C. achieving other significant public health purposes for a disease or syndrome that can cause serious morbidity or mortality." The proposed rule also specifies that the Commissioner will select sites based upon a consideration of the potential number of cases at the site; the geographic distribution of cases or potential cases in Minnesota, if indicated by the epidemiology of the disease or syndrome; the epidemiology of the disease or syndrome; and the overall impact of sentinel surveillance on a site and the benefit to public health in conducting sentinel surveillance at the site. The Commissioner is required to consult with the site before making a selection. The Department indicated at the rule hearing that the Department engaged in extensive discussions with the Advisory Committee about the purpose, use and value of sentinel surveillance and obtained input from the members about what criteria should be used for selection of the sites.[48]

68. The Department explained in its SONAR that, despite the fact that it already conducts sentinel surveillance and has authority to do so under Minn. Stat. § 144.05, it determined that this new rule part was necessary because of HIPAA and the reluctance of some health care providers to participate because of the new federal privacy rules. Despite the fact that HIPAA allows disclosure of protected health information to public health authorities for public health purposes, the Department

indicated that those who report disease increasingly want assurance that there is explicit authority for them to report. The proposed rules are intended to provide that explicit authority. The Department currently conducts sentinel surveillance to monitor vaccine effectiveness (influenza) and to characterize infectious disease pathogens in the community (influenza and MRSA). If the rule is adopted, the Department anticipates that it will continue conducting sentinel surveillance for influenza and MRSA and that it will also conduct sentinel surveillance for varicella zoster disease (chickenpox) because, despite the fact that case-based reporting would be burdensome at the present time, the Department believes that there is a need to monitor the effectiveness of the new vaccine and shifts in the epidemiology of the disease.

69. Dr. Bearmon objected to the sentinel surveillance portion of the proposed rules on the ground that the Department will be able to collect private patient medical record data on any disease or condition it chooses for sentinel surveillance. CCHC objected to sentinel surveillance since sites and diseases would be selected at the Commissioner's discretion and without any notice to the public and request for comments. CCHC contends that sentinel surveillance "gives MDH unprecedented power to require patient data."

70. Dr. Holton supported sentinel surveillance as a means of decreasing the reporting burden on physicians while still enabling the Department to effectively monitor large outbreaks.[49] Mr. Kellogg also supported the use of sentinel surveillance as avoiding the extensive invasion of privacy associated with broader reporting requirements.[50]

71. The proposed rules set forth criteria as to when the Commissioner may conduct sentinel surveillance for a disease or syndrome and require consultation with the site prior to selection as well as consideration of the overall impact on the site and the benefit to public health. The proposed rules also require that the surveillance be "necessary" for achieving "significant public health purposes for a disease or syndrome that can cause serious morbidity or mortality," thereby specifying some standards for disease selection. The Administrative Law Judge concludes that the Department has shown that the sentinel surveillance provision is necessary and reasonable to assist the Department in monitoring infectious disease pathogens, the effectiveness of vaccine, and responding to other significant public health problems.

Part 4605.7050 – Unusual Case Incidence

72. Part 4605.7050 of the rules addresses reporting requirements with respect to patterns of cases or increased incidence of illness that may signal an outbreak, new infectious agent, or other public health hazard. Under the proposed rules, persons having knowledge would be required to make immediate telephone reports to the Commissioner concerning cases of "emerging drug resistance." CCHC and Dr. Bearmon objected to requiring reports on individuals who are or may be experiencing antibiotic resistance. David Wallinga, M.D., asserted that the connections between antibiotic resistance and antibiotic use in agriculture should be specifically addressed by the antibiotic surveillance information collected by the Department, in light of recent

studies suggesting that cases of resistant infection involving non-typhoidal Salmonella and E coli urinary tract infection are most likely directly linked to the overuse of antibiotics in farm animals.

73. In the SONAR,[51] the Department indicated that it is proposing to add "emerging drug resistance" to the conditions under which a pattern of cases, suspected cases or increased incidence of cases must be immediately reported because of the growth in the number of pathogens that are resistant to antibiotics and other drugs. For example, the Department indicated that a recent increase in antibiotic resistant strains of *Streptococcus pneumoniae* has made treating the disease more difficult and has increased severe illness. The fact that some drugs currently used to treat certain infections are not effective is a public health problem because these resistant strains can spread from person to person. The Department indicated that it is critical to identify emerging resistance in order to alert clinicians who prescribe antibiotics and institute control measures to contain spread of the resistant organism. The Administrative Law Judge finds that the Department has shown that the proposal to encompass "emerging drug resistance" in the proposed rules is needed and reasonable. While the Department is free to consider Dr. Wallinga's suggestions in reviewing information received under the proposed rule, the proposed rule is not rendered unreasonable or defective in any way by its failure to expressly mention potential causes of drug resistance.

74. This part of the existing rules requires that any unexplained death which may be caused by an infectious agent must be reported to the Commissioner within one day. The proposed rules also would add the requirement that "unexplained critical illness in a previously healthy individual" which may be caused by an infectious agent also be reported by the attending physician, medical examiner or coroner, or a person having knowledge. "Critical illness" is defined to mean "the condition of a person who is hospitalized in an intensive care unit or who is critically ill in the judgment of a licensed health care provider."[52] CCHC objected to required reports concerning unexplained critical illness based on an apparent claim that this category is overbroad. In its SONAR, the Department explained that this modification was proposed in order to ensure that the Department is able to monitor possible new and emerging diseases and possible bioterrorism situations. The definition of critical illness clarifies situations in which the proposed rule is intended to apply. The Department has shown that this portion of the proposed rule is needed, reasonable, and consistent with its statutory authority.

Part 4605.7080 – New Diseases and Syndromes; Reporting and Submissions

75. The amendments modify the existing rules to specify that the Commissioner shall, by public notice, "require" (rather than "request") reporting of newly recognized or emerging diseases "and syndromes suspected to be of infectious origin or previously controlled or eradicated infectious diseases if: A. the disease or syndrome can cause serious morbidity or mortality; and B. report of the disease or syndrome is necessary to monitor, prevent, or control the disease or syndrome to

protect public health." Dr. Bearmon objected to permitting the Department to "require" reporting rather than just "request" reporting.

76. In its SONAR, the Department explained that the proposed rules would change the word "request" to "require" so that the Commissioner is given authority to ensure that infectious diseases or syndromes that could endanger the public's health are, in fact, reported. The Department pointed out that it must often work very quickly to control or prevent a possible disease outbreak or epidemic, particularly in times in which international travel is common and acts of bioterrorism are possibilities. When the Commissioner issued a public notice requesting reporting of SARS in 2003, questions were raised concerning why the notice used the word "request" rather than "require." Because the public's health could be jeopardized if mandated reporters viewed a "request" to report to be discretionary, the Department is proposing to require such reports as part of the proposed rule.

77. The Administrative Law Judge concludes that the Department has shown that this portion of the proposed rule is needed and reasonable to make certain that infectious diseases or syndromes are reported when the Commissioner issues a public notice imposing that requirement.

Part 4605.7090 – Disease Report Information

78. Part 4605.7090 of the proposed rules specifies that those reporting diseases under chapter 4605 must include certain information in their report, to the extent such information is known. The primary changes made by the proposed rules to this subpart of the existing rules would require the reporting of the patient's gender, vaccination history for the disease reported, and pregnancy status and expected date of delivery, if the infection can be transmitted during pregnancy or delivery. The proposed rules also seek to modify the existing rule to refer to "ethnic and racial origin" rather than "ethnic or racial origin." As discussed below, several members of the public objected to these modifications.

Gender and Ethnic and Racial Origin

79. CCHC objected to the inclusion of reporting requirements in item (D), subitems (3) and (4), relating to race, ethnicity, and gender. CCHC asserted that these descriptions have not been required in the past, this information is not necessary to count and report the number or location of diseases, and such information would be used by the Department for research rather than disease surveillance. CCHC also argued that there is no commonly-agreed-upon definition of race or ethnicity and questioned whether there is statutory authority for the Department's proposed rule.

80. The Minnesota AIDS Project commented that the collection of information about gender is of critical importance since gender can make a significant difference in how disease is experienced. MAP also supported providing the Department with the flexibility to collect other relevant behavioral information to help understand disease transmission and develop strategic public health responses. In MAP's view, "[t]he

aggregated demographic and behavioral information collected through public health is *absolutely essential* to our agency's efforts to stop HIV infections in Minnesota [since] it allows us to target limited resources to reach communities with the highest risk, and it enables us to tailor our prevention messages to ensure that they are culturally and behaviorally relevant." (Emphasis in original.)

81. The Department said that Advisory Committee members asked why gender was not included in the list of information to be reported, and the Department realized that it was an oversight because the Department does collect this information. The Department indicated that reporting of gender is necessary and reasonable because patterns of disease can vary by gender and it is important to take that into consideration in targeting prevention and control efforts[53] The Department also pointed out that the existing rules already call for collection of data about race and ethnicity. The only modification made by the proposed rules in this regard was to change the wording to require submission of information about "ethnic and racial origin" rather than information about "ethnic or racial origin." The Department explained that the change was proposed because race and ethnicity are different factors and both are needed to identify patterns of disease in the population and assist in targeting interventions. The Department indicated that this change also reflects the standards of the federal Office of Management and Budget and the U.S. Census for the classification of federal data on race and ethnicity.

82. The Department has shown that it is necessary and reasonable to collect information relating to gender and ethnic and racial origin as part of disease reports.

Vaccination History

83. CCHC objected to item (K) of the proposed rules, which calls for the collection of vaccination history for the disease reported, on the grounds that the Department would be conducting surveillance of medical treatment and not disease. For illnesses with unknown causes, or for illnesses unrelated to a disease for which a vaccine is available, CCHC contends that it is likely that an individual's entire vaccination history will be reported, and asserts that the Department is attempting to conduct vaccination-related research. Dr. Bearmon also objected to this portion of the proposed rules.

84. In its SONAR, hearing testimony, and post-hearing submissions, the Department explained that the purpose for conducting surveillance of vaccine-preventable diseases encompasses not only the monitoring of disease activity but also identifying unvaccinated populations at risk for contracting such diseases, for prevention and outbreak control. The collection of vaccination history will allow the Department to differentiate between cases where there was vaccination failure and those where the person was not vaccinated, and permit the Department to monitor vaccine failures and know if target populations are receiving vaccines. For example, the Department indicated that, when measles outbreaks occurred in highly vaccinated populations nationwide during the 1980s, it was determined that a second dose of vaccine was

needed to prevent further spread of the disease. As a result of a two-dose schedule, fewer than 50 cases of measles were reported nationally during 2003.

85. The Administrative Law Judge concludes that the proposed collection of vaccination history for the particular disease at issue has been shown to be needed and reasonable to permit the Department to monitor vaccine failures and determine whether target populations are receiving vaccine.

Pregnancy Status and Expected Date of Delivery

86. Item (L) of the proposed rules asks for reports of "pregnancy status and expected date of delivery, if the infection can be transmitted during pregnancy or delivery." CCHCobjected to the reporting ofpregnancy status under item (L) as an "unprecedented policy change" that establishes the Department as "the prenatal educator of expectant moms." CCHC expressed concern that the Department will engage in treatment surveillance, and will intrude on the family and take the place of the physician before any disease has been transmitted. CCHC believes that the Department lacks statutory authority for the proposed rule provision. CCHC also suggested that, due to successes in reducing the transmission of HIV from mother to infant, the proposed rule change is unnecessary. Dr. Bearmon also objected to pregnancy and due date becoming a reportable condition for women known to have certain chronic diseases. Edna Jensen commented that the state has no need to know a woman's pregnancy and due date or any other condition of the woman or her child, and stated that the "government is not a medical team that can be of any benefit to the patient." She found this to be an invasion of privacy. Edite Donatelle and Jan Antinozzialso objected to the reporting of pregnancy and due date as a violation of privacy and patient rights. Dr. Gregory Sheehan objected to the proposed rule based upon a concern that mandatory reporting of health conditions will cause patients to withhold information and avoid prenatal care, and that such an outcome will pose as much danger to the unborn child as the risk of disease transmission.

87. The Minnesota AIDS Project supported the reporting of pregnancy status. MAP noted that pregnant women need information about how to prevent transmission of HIV infection so that they can make treatment choices. Reporting pregnancy status will be beneficial, in the view of MAP, since such reporting will create an opportunity to ensure that health care providers (with the assistance of public health staff, where necessary) provide treatment information that can virtually eliminate the risk of HIV infection.

88. In the SONAR, hearing testimony, and post-hearing responses, the Department emphasized that the proposed modification does not make all pregnancies a reportable condition, but merely calls for reports of pregnancy for a woman with an infectious disease that can be transmitted from mother to infant during pregnancy or delivery. The Department stressed that it is proposing the reporting of pregnancy for perinatally-transmissible diseases not only for the purposes of education of the mother, but also to monitor implementation of perinatal disease prevention guidelines. The Department indicated that this reporting allows the Department to monitor intervention

efforts to prevent infection in the infant and ensure coordination between public health and private health care providers, in order to facilitate the prevention of transmission of the disease. The Department indicated that the pregnancy status of women with HIV/AIDS has long been routinely collected throughout the United States and asserted that it is in part because of this reporting that mother-to-infant transmission of HIV has been nearly eliminated in the U.S. The Department explained that women represent increasing proportions of annual HIV cases and the number of women living with HIV in Minnesota has increased steadily over time, resulting in a parallel increase in the number of births to HIV-infected women. There were 49 infants born to HIV-infected mothers in Minnesota during 2004, as compared to only 9 during 1990. The risk of mother-to-child HIV transmission is 25- to 30-percent without treatment, but less than 2 percent with treatment. The Department further stated that perinatal transmission of hepatitis B from mother to infant at birth may be as high as 70- to 90-percent without preventive medical care, and up to 90 percent of perinatally-infected infants who do not receive prophylaxis will develop a chronic hepatitis B infection. Moreover, 15- to 25-percent of those persons will ultimately develop liver failure, liver cirrhosis, or primary liver cancer. Prophylaxis within 12 hours of birth is 90 percent effective at preventing hepatitis B infection in infants. The Department emphasized that the role of public health under state law is to coordinate and facilitate services for the prevention and control of disease, and asserted that this role will be accomplished by coordinating activities between the health care provider who is following the mother during pregnancy, providers at the birthing hospital, and the infant's health care provider following discharge from the hospital.[54] The Department also contends that the rule is not a change in policy but is consistent with directives from the Legislature that the Department provide consultation and technical training to professionals who treat people with diseases,[55] act as an educator of pregnant women,[56] and act as an educator of local public health agencies and organizations around the state involving sexually transmitted infections such as HIV and hepatitis B.[57]

89. The Administrative Law Judge concludes that the reporting of pregnancy status under the circumstances specified in the proposed rule has been shown to be needed and reasonable to ensure education of the mother and her health care provider concerning treatment options and enable the Department to monitor implementation of perinatal disease prevention guidelines.

Part 4605.7500 – Disease Investigations

90. The proposed rules amend the existing rules to indicate that the Commissioner "shall investigate the occurrence of cases, suspected cases, or carriers of reportable diseases or unusual disease occurrences in a public or private place for the purpose of verification of the existence of disease, ascertaining the source of the disease causing agent, identifying unreported cases, locating and evaluating contacts of cases and suspected cases, identifying those at risk of disease, determining necessary control measures, and informing the public if necessary." (Proposed amendments are underlined.)

91. In its SONAR,[58] the Department explained that disease investigation currently may include contacting contacts of cases to inform them that they have been exposed to a reportable disease or condition. For some diseases, such as hepatitis B and tuberculosis, the Department not only needs to locate the contact but also evaluate the contact for the presence of the infection through interviews, review of existing test results, or recommendations for additional testing. This helps to ensure that the contact will get appropriate tests and treatment to prevent the disease from spreading to others. For example, a contact who has a positive Mantoux test but does not have active tuberculosis can be given antibiotics to prevent development of an active infection. The SONAR indicates that this type of follow-up is a standard part of public health tuberculosis prevention programs throughout the United States. The term "evaluating" was added to the rule provision to clarify this function. The phrase "suspected cases" was added to make this part consistent with the remainder of the rule and to ensure that the Department is able to conduct a thorough disease investigation and implement appropriate control measures even while it is awaiting test results or disease confirmation.

92. CCHC commented that the addition of the word "evaluating" to the rule part implies a significant shift of power to the government and could possibly lead to forced testing and treatment of contacts. CCHC noted that the term is not defined and raised objections regarding intrusiveness and statutory authority. Dr. Bearmon also raised the concern that the Department may be able to coerce individuals into testing and treatment by virtue of this portion of the proposed rules, asserting that the 2002 Legislature rejected the Department's authority to ensure that contacts get appropriate tests and treatment.

93. In response, the Department indicated that it has clear statutory authority to conduct disease investigations under Minn. Stat. § 144.05[59] and clarified that the proposed amendment was not intended to confer any authority to coerce individuals into testing and treatment. However, because the changed language could be misinterpreted, the Department proposed in its post-hearing comments to modify this language to clarify the Department's intent. As modified, part 4605.7500 would read as follows:

> The commissioner shall investigate the occurrence of cases, suspected cases, or carriers of reportable diseases or unusual disease occurrences in a public or private place for the purpose of verification of the existence of disease, ascertaining the source of the disease causing agent, identifying unreported cases, locating <u>and evaluating</u> contacts of cases <u>and suspected cases by assessing relevant risk factors, and testing and treatment history</u>, identifying those at risk of disease, determining necessary control measures, and informing the public if necessary.

94. The language of the proposed rule, as modified, has been shown to be needed and reasonable to ensure that the Department is able to conduct a thorough disease investigation. The modification clarifies the Department's intent to evaluate contacts by assessing relevant risk factors and the contact's testing and treatment

history, and does not result in a rule that is substantially different from the rule as originally proposed. Although it is not a defect in the rule, the Administrative Law Judge suggests that understanding of the rule would be facilitated if the comma after the word "factors" were deleted.

Based on the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Minnesota Department of Health gave proper notice in this matter.

2. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 4 and 14.50 (iii).

5. The additions and amendments to the proposed rules suggested by the Department after publication of the proposed rules in the State Register are not substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.05, subd. 2, and 14.15, subd. 3.

6. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

7. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that the rule finally adopted is based upon facts as appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed amended rules be adopted, except where noted otherwise.

Dated: April 13, 2005.

s/Barbara L. Neilson

BARBARA L. NEILSON
Administrative Law Judge

Transcript Prepared by Paradigm Reporting & Captioning, Inc., (612) 339-0545.

[1] Minn. Stat. §§ 14.131 through 14.20.
[2] Minn. Stat. § 14.15, subd. 1.
[3] See Statement of Need and Reasonableness at 2.
[4] *Mammenga v. Department of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Housing Institute v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).
[5] *In re Hanson*, 275 N.W.2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362, 367, 43 N.W.2d 281, 284 (1950).
[6] *Greenhill v. Bailey*, 519 F.2d 5, 19 (8th Cir. 1975).
[7] *Mammenga*, 442 N.W.2d at 789-90*; Broen Memorial Home v. Minnesota Department of Human Services,* 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).
[8] *Manufactured Housing Institute*, 347 N.W.2d at 244.
[9] *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 233 (1943).
[10] Minn. R. 1400.2100.
[11] *See* Minn. Stat. § 14.15, subd. 3, and 14.05, subd. 2.
[12] Minn. Stat. § 14.05, subd. 2.
[13] Ex. A.
[14] SONAR at 2 and Attachment B.
[15] Ex. E; Minn. Stat. § 14.131 and Minn. R. 1400.2220, subp. 1(E).
[16] Ex. G.
[17] Ex. H.
[18] Ex. H.
[19] Ex F.
[20] Ex. H.
[21] Ex. H.
[22] Ex. K; *see also* April 11, 2005, e-mail from P. Segal Freeman to M. Lindstrom.
[23] Ex. I.
[24] Ex. K.
[25] Minn. Stat. §§ 14.116 and 14.14.
[26] *See* SONAR at 16-17; Exs. H, K; Feb. 14, 2005, e-mail from A. Leitheiser to T. Brase.
[27] *Schulte v. Fitch*, 202 N.W. 719, 721 (Minn. 1925).
[28] *See* SONAR at 4-14.
[29] Minn. Rules 4605.7090.
[30] Hearing Transcript at 52-54.
[31] Hearing Transcript at 59.
[32] Hearing Transcript at 62.
[33] *See* Ex. I.
[34] Minn. Stat. §§ 13.04 and 13.3805.
[35] Ex. L.
[36] Ex. N.
[37] Hearing Transcript at 35.
[38] Ex. L.
[39] Ex. L.
[40] Hearing Transcript at 41.
[41] Hearing Transcript at 37-38.
[42] Minn. Stat. § 13.3805(b)(2).
[43] See 45 C.F.R. Part 46.

[44] U.S. centers for Disease Control and Prevention, “Guidelines for Defining Public Health Research and Public Health Non-Research.”
[45] Ex. L.
[46] Ex. N.
[47] See proposed rule part 4605.7000, subp. 12.
[48] Hearing Transcript at 28; SONAR at 52-54.
[49] Hearing Transcript at 39.
[50] Hearing Transcript at 59.
[51] SONAR at 55.
[52] See Part 4605.7000, subp. 6, of the proposed rules.
[53] Hearing Transcript at 26; SONAR at 58.
[54] Minn. Stat. § 144.05, subd. 1(b), states that the Commissioner of Health has authority to “[p]lan, facilitate, coordinate, provide, and support the organization of services for the prevention and control of illness and disease and the limitation of disabilities resulting therefrom . . . .”
[55] Minn. Stat. § 144.05, subd. 1(d) states that the Commissioner has authority to “[a]ffect the quality of public health and general health care services by providing consultation and technical training for health professionals and paraprofessionals . . . .”
[56] Minn. Stat. § 144.06 specifies that the Commissioner of Health is “authorized to provide instruction and advice to expectant mothers and fathers during pregnancy and to mothers, fathers, and their infants after childbirth . . . .”
[57] Minn. Stat. § 144.065 states that the Commissioner of Health “shall assist local health agencies and organizations throughout the state with the development and maintenance of services for the detection and treatment of sexually transmitted infections”; that these services “shall provide for research, screening and diagnosis, treatment, case finding, investigation, and the dissemination of appropriate educational information”; and that the Commissioner “shall provide technical assistance to such agencies and organizations in accordance with the needs of the local area.”
[58] SONAR at 59.
[59] For example, Minn. Stat. § 144.05, subd. 1(a) states that the Commissioner has authority to “[c]onduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems . . . .”